K131037

5.0 510(k) SUMMARY

SUBMITTED BY:

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SEP 06 2013

NAME OF DEVICE:

Trade Name:	LIAISON® XL HCG
Common Names/Descriptions:	Human Chorionic Gonadotropin (hCG)
Classification Names:	Human Chorionic Gonadotropin (hCG) test system
Product Code:	DHA

PREDICATE DEVICE: Roche ELECSYS® HCG +Beta Test Reference K003178

DEVICE DESCRIPTION:

INTENDED USE:
The DiaSorin LIAISON® XL HCG assay uses chemiluminescent immunoassay (CLIA) technology on the LIAISON® XL Analyzer for the quantitative determination of total human chorionic gonadotropin (hCG and βhCG) in human serum for early detection of pregnancy. Total hCG is the measurement of intact and beta-hCG.

KIT DESCRIPTION:
The method for the quantitative determination of hCG is a sandwich chemiluminescence immunoassay. A specific mouse monoclonal antibody is coated on the magnetic particles (solid phase); another monoclonal antibody is linked to an isoluminol derivative (isoluminol-antibody conjugate). All assay steps and incubations are performed by the LIAISON® XL Analyzer.

During the first incubation, hCG present in calibrators, samples or controls binds to the solid phase monoclonal antibody, and subsequently after a washing step in a second incubation the antibody conjugate reacts with hCG already bound to the solid phase.

Subsequently, the starter reagents are added and a flash chemiluminescence reaction is thus induced. The light signal, and hence the amount of isoluminol-antibody

conjugate, is measured by a photomultiplier as relative light units (RLU, relative light units) and is directly related to hCG concentration present in calibrators, samples or controls.

COMPARISON TO PREDICATE DEVICE:

The DiaSorin LIAISON® XL HCG assay is substantially equivalent in principle and performance to the Roche Elecsys® HCG +Beta Test (K003178) which was FDA cleared December 14, 2002.

Table 1: Table of Similarities

Characteristic	New Device LIAISON® XL HCG	Predicate Device Roche ELECSYS® HCG + Beta Test System (K003178)
Intended Use	*In-vitro* assay for the quantitative determination of total human chorionic gonadotropin (hCG and βhCG) in human serum for early detection of pregnancy using the LIAISON® XL Analyzer.	Immunoassay for the *in-vitro* quantitative determination of the sum of human chorionic gonadotropin (hCG) plus the hCG Beta subunit in human serum and plasma.
Indications for Use	For the early detection of pregnancy.	For the early detection of pregnancy.
Measured Analyte	human chorionic gonadotropin (hCG) plus the hCG Beta subunit	human chorionic gonadotropin (hCG) plus the hCG Beta subunit
Assay Type	Chemiluminescent Immunoassay	Electrochemiluminescent Immunoassay
Test principle	Sandwich chemiluminescent Immunoassay	Sandwich chemiluminescent Immunoassay
Solid Support	Paramagnetic particles coated with recombinant hCG	Paramagnetic particles coated with streptavidin and coupled to biotinylated monoclonal hCG-specific antibodies
Reagent Integral Storage	On-board or in refrigerator@ 2-8°C	On-board or in refrigerator@ 2-8°C
Sample Handling/Processing	Automated	Automated
Unit of Measure	mIU/mL	mIU/mL
Traceability	3rd WHO reference standard IS 75/537.	3rd WHO reference standard IS 75/537.

Table 2 : Table of Differences		
Characteristic	**New Device LIAISON® HCG**	**Predicate Device Roche ELECSYS® HCG + Beta Test System (K003178)**
Instrument	LIAISON® XL Analyzer	Roche Elecsys® Immunoassay analyzer
Calibration	Two-point calibrator verification of stored master curve. Included with the kit.	Two-point calibrator verification of stored master curve. Not included with the kit.
Measuring range	1.5 – 10,000 mIU/mL	0.100 – 10,000 mIU/mL
Sample Matrix	Human serum	Human serum and plasma
Sample size	30 µL	10 uL
Conjugate Antibody	Anti-hCG antibodies (mouse) labeled with isoluminol	Biotinylated monoclonal anti-hCG antibodies (mouse)
Open storage 2-8°C	4 weeks	12 weeks
Controls	No Controls Provided	2 Levels

PERFORMANCE DATA:

Method Comparison:
One hundred sixty-three (163) serum samples, that spanned the reportable range of the assay, were tested and analyzed by Weighted Deming Regression. The method comparison study was performed according to CLSI EP9-A2 guideline.

Results:
Weighted Deming Regression analysis was performed on the results across the range of LIAISON® XL HCG assay yielding agreement of y= 0.973x - 0.2233; R^2 = 0.9933.

Reference Range/Expected Values:
The reference range study was performed according to CLSI Approved Guideline C28-A3. Human serum samples from apparently healthy non-pregnant premenopausal and postmenopausal subjects were tested to determine the reference range for the LIAISON® XL HCG assay. The results are listed below:
· In a study performed on 74 healthy, non-pregnant premenopausal women (<50 years old), 97.5% of the values obtained were below 1.54 mIU/mL hCG.
· In a study performed on 70 healthy, postmenopausal women (≥ 50 years old), 97.5% of the values obtained were below 6.67 mIU/mL hCG.
Consider these limits as guidelines only. It is important for each laboratory to establish its own reference range, representative of its typical population.

Reproducibility/Precision:
A twenty day reproducibility/precision study was performed at DiaSorin Inc. A coded panel comprised of 6 frozen serum samples was prepared by DiaSorin Inc. The coded panel contained levels of low, medium and high samples. Commercial controls (3

levels) were also tested in the study. The CLSI document EP05-A2 was consulted in the preparation of the testing protocol.

Results

The twenty day results are summarized in the following table as sample overall mean HCG concentration in mIU/mL, computed SDs and %CVs for within run and total across lots.

Panel ID#	N	mean mIU/mL	Between Lot SD	Between Lot %CV	Total SD	Total %CV
QC1	160	6.4	0.02	0.3%	0.68	10.7%
QC2	160	23.3	0.07	0.3%	1.41	6.0%
QC3	160	175.1	2.31	1.3%	6.04	3.5%
HCG-11	160	60.2	0.01	0.0%	2.95	4.9%
HCG-12	160	25.5	0.31	1.2%	1.60	6.3%
HCG-13	160	431.4	6.44	1.5%	13.03	3.0%
HCG-14	160	893.2	15.85	1.8%	28.97	3.2%
HCG-15	160	4169.0	72.01	1.7%	153.66	3.7%
HCG-16	160	9607.6	29.89	0.3%	298.61	3.2%

Dilution Linearity:

Two serum pools containing high hCG concentrations were tested neat and after serially diluting following CLSI EP6-A.

The results were analyzed by a Weighted Deming fit of observed hCG concentration versus expected hCG concentration.

Both sample sets yielded similar linear regressions. An example is shown below: $Y_{(\text{obtained mIU/mL})} = 1.0158X_{(\text{expected mIU/mL})} - 0.1450$

LoB/LoD/LoQ:

The Limit of Blank, Limit of Detection and Limit of Quantitation were determined according to CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline June 2012- Second Edition.

Results:

Limit of Blank: 0.17 mIU/L
Limit of Detection: 0.36 mIU/L
Limit of Quantitation: 1.5 mIU/L

Recovery

A recovery study using five levels of spiked samples, which were prepared by adding the targeting amount of WHO 3rd reference standard into five human sera and tested in duplicates using one lot of reagents on one instrument, was conducted. The overall % recovery for each spiked level was determined and are tabulated below.

Spiked level (mIU/mL)	Overall %recovery
5	91.8
25	105.9
500	94.9
5000	92.9
9000	96.9

Interfering Substances:

Controlled studies of potentially interfering substances at two hCG levels showed no interference at the concentration for each substance listed below in the LIAISON® XL HCG assay. The testing was based on CLSI-EP7-A2.

Substance	Highest Concentration Tested
Triglycerides	3000 mg/dL
Hemoglobin	1000 mg/dL
Unconjugated bilirubin	20 mg/dL
Conjugated bilirubin	20 mg/dL
Albumin	6 g/dL
Rheumatoid Factor	194 IU/L
Luteinizing Hormone (LH)	500 mIU/mL
Follicle-stimulating hormone (FSH)	500 mIU/mL
Human Growth Hormone (hGH)	100 ng/mL
TSH	200 mIU/mL
Acetaminophen	20 mg/dL
Acetylsalicylic Acid	20 mg/dL
Ascorbic Acid	20 mg/dL
Atropine	20 mg/dL
Caffeine	20 mg/dL
EDTA	80 mg/dL
Ethanol	1%
Gentisic Acid	20 mg/dL
Glucose	2 g/dL
Salicylic Acid	20 mg/dL

CONCLUSION:

The material submitted in this premarket notification is complete and supports the basis for substantial equivalence to the Roche ELECSYS® HCG + Beta Test System (K003178). The labelling is sufficient and satisfies the requirements of 21 CFR Part 809.10.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 6, 2013

DiaSorin Inc.
C/O Mari Meyer
Director, Regulatory Affairs
1951 Northwestern Avenue
P.O. Box 285
STILLWATER MN 55082

Re: K131037
Trade/Device Name: DiaSorin LIASON® XL HCG
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: II
Product Code: DHA
Dated: August 14, 2013
Received: August 21, 2013

Dear Ms. Meyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k131037

Device Name: LIAISON® XL HCG

Indications for Use: The DiaSorin LIAISON® XL HCG assay uses chemiluminescent immunoassay (CLIA) technology on the LIAISON® XL Analyzer for the quantitative determination of total human chorionic gonadotropin (hCG and βhCG) in human serum for early detection of pregnancy. Total hCG is the measurement of intact and beta-hCG.

Prescription Use __X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S
2013.09.06 07:55:38 -04'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

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